

Brief Cognitive-Behavioral Therapy for Suicide Prevention in a Brazilian Outpatient Sample (BCBT-BR): Protocol for a Two-Arm Randomized Controlled Trial

Short title: BCBT-BR Trial Protocol

Date: May 4th, 2026

Abstract

Importance: Suicide remains a leading cause of premature mortality worldwide. While global rates have declined since 2000, the Region of the Americas shows concerning increases, particularly in Brazil. Brief Cognitive-Behavioral Therapy (BCBT) has demonstrated efficacy in reducing suicide attempts in high-income countries, but evidence from low- and middle-income countries (LMICs) and civilian outpatient settings remains limited.

Objective: To evaluate whether BCBT reduces suicide attempt incidence over 6 months compared with manualized Supportive Psychotherapy (ST) among high-risk Brazilian adults receiving university outpatient care.

Design, Setting, and Participants: Single-site, parallel-group, superiority randomized clinical trial (RCT) at the Institute of Psychiatry, University of São Paulo, Brazil. Adults aged 18-65 years with current suicidal ideation and/or suicide attempt within the past month will be randomized 1:1 to receive 12 weekly 60-minute sessions of BCBT or dose-matched ST (N=150; 75/group).

Interventions: BCBT targeting emotion regulation and cognitive reappraisal versus manualized ST providing emotional support without systematic skills training.

Main Outcomes and Measures: Primary outcome is time-to-first suicide attempt over 6 months, assessed by blinded evaluators. Secondary outcomes include suicidal ideation, non-suicidal self-injury, depression, anxiety, treatment feasibility and acceptability. Assessments occur at baseline, mid-treatment (week 6), end-of-treatment (week 12), and 3- and 6-month follow-ups, with weekly attempt surveillance. Intention-to-treat analyses will employ Cox proportional hazards regression (primary outcome) and mixed-effects/generalized linear models (secondary outcomes). Sample size provides 80% power to detect HR=0.50 ($\alpha=0.05$, 25% attrition).

Conclusions and Relevance: This trial will provide critical evidence on BCBT effectiveness in LMIC outpatient settings, informing scalable suicide prevention strategies.

Trial Registration: ClinicalTrials.gov: [Registration pending – the ethics approval identifier CAAE 88755725.9.0000.0068 (CONEP/Plataforma Brasil) is reported separately under Ethics Approval; the prospective trial registry number will be updated upon confirmation] 88755725.9.0000.0068

Ethics Approval: CONEP/Plataforma Brasil CAAE 88755725.9.0000.0068.

Keywords: suicide attempt; suicidal ideation; brief cognitive-behavioral therapy; supportive psychotherapy; randomized controlled trial; Brazil; LMICs.

Introduction

Suicide figures as a major public health-related outcome and as one of the main causes of premature mortality (O'Connor et al., 2023). According to World Health Organization (WHO) data, more than 720,000 deaths by suicide are registered worldwide each year (World Health Organization, n.d.). Considering the alarming numbers, WHO has set the reduction of suicide mortality as a priority in the United Nations Sustainable Development Goals (SDGs), as well as in WHO's 13th General Programme of Work 2019–2023 and in the WHO Mental Health Action Plan 2013–2022, which has been extended to 2030 (World Health Organization, 2021). WHO (2021) states that an articulated response to suicide prevention is urged as this outcome costs millions of lives and burdens suicide-exposed people, affected by those who have attempted or died by suicide (World Health Organization, 2021). Each death by suicide affects on average more than 130 people, who may further need clinician support after being exposed to suicide grief (Cerel et al., 2016).

In 2019, the global age-standardized suicide rate was 9.0 per 100,000 population, and in Brazil, the suicide rate was 6.7 per 100,000 inhabitants (World Health Organization, 2021). In 2021, a significant majority of suicides - 73% - occurred in low-and-middle-income countries (LMICs) (World Health Organization, n.d). This data explains the urgent need for effective suicide prevention strategies in LMICs, including Brazil, where suicide is a growing public health concern. Despite the Brazilian rate being inferior to the global age-standardized rate in 2019, other alarming data highlight the urgency of addressing this public health issue in Brazil. Regardless of the 36% global reduction in the numbers of suicides from 2000 to 2019 (Damiano et al., 2024), some countries, such as Brazil, still face the challenge to address rising numbers. The Americas region has demonstrated a 17% increase in the same period, and Brazil figures as one of the countries with the most significant rise (43%) (World Health Organization, 2021). According to the most recent epidemiological bulletin released by the Brazilian government, from 2000 to 2021, there was a 42% increase in the suicide mortality rate, from 5.2 to 7.5 per

100,000 inhabitants (Brasil, Ministério da Saúde, Secretaria de Vigilância em Saúde e Ambiente, 2024).

Brief Cognitive Behavioral Therapy

CBT for suicide prevention protocols are designed to help high-risk individuals to identify patient-specific factors that trigger and intensify suicidal thoughts and behaviors, as well as to develop effective coping strategies when dealing with stressors and problems that activate the suicidal mode (Mann et al., 2021; Bryan & Rudd, 2018).

In BCBT, to reach those goals, treatment is composed of three main phases, as follows: Emotional Regulation and Crisis Management, Targeting Belief Systems Related to Suicide and Relapse Prevention (Bryan & Rudd, 2018). See table 1 in Supplementary Material. The first phase focuses on developing effective strategies for regulating intense emotions and managing crises in a manner that is adaptive (Bryan & Rudd, 2018). During this stage, the objective is to help the patient identify emotional triggers and learn mindfulness techniques to promote assertive responses to stressful situations. The development of an individualized action plan to address critical moments with greater emotional control is considered to be essential for therapeutic progress (Bryan & Rudd, 2018).

The second phase centers on identifying and modifying the negative and distorted thought patterns that underlie suicidal ideation. Through cognitive restructuring, the goal is to cultivate a more realistic and adaptive view of oneself and the future, while enhancing emotional resilience. Addressing belief systems related to suicide is a critical component of the therapeutic process, as these beliefs are often linked to suicidal behavior (Bryan & Rudd, 2018).

The final phase emphasizes relapse prevention, focusing on identifying risk factors that may trigger the return of suicidal thoughts. Personalized preventive strategies will be developed, including strengthening social support networks, continuous practice of coping skills, and creating a detailed contingency plan to handle potential future adversities. The aim is to equip the patient with robust tools to maintain mental

health and well-being in the long term, thereby reducing the likelihood of recurrent suicidal crises (Bryan et al., 2024).

Supportive psychotherapy

Concerning control treatment characteristics in suicidology, approximately 60% of the Randomized Controlled Trials across nearly 50 years of research had their active treatment condition compared to active control conditions, such as psychotherapy suicidality (Fox et al., 2020); however, the chosen psychotherapy approach as a comparator was not specified in this analysis.

There has been a historical debate between researchers and clinicians about the understanding of what makes psychotherapy work. This debate could be summarized in the conflict existing among two main groups: those who believe that the therapy's efficacy depends solely on the common factors, and the other group that defends the insertion of the specific factors (Wampold, 2015).

Common factors refer to the elements that can be found in various psychotherapeutic approaches and are believed to contribute to the effectiveness of therapy, regardless of the specific techniques derived from their philosophical and conceptual basis. These factors include elements such as the therapeutic alliance, empathy, positive regard, and the client's expectations of therapy, among others (Norcross & Lambert, 2011).

Specific factors, on the other hand, according to Norcross & Lambert (2011), can be defined as the techniques and interventions unique to particular therapeutic approaches and designed to address specific goals concerning psychological issues. For example, one of the instruments developed by CBT is the Dysfunctional Thought Record, and its particular goal is to help patients identify and restructure their dysfunctional thoughts. According to CBT's postulates, by doing so, patients can better understand the connection between their thoughts, emotions, and behaviors, leading to more adaptive ways of thinking that allow them to feel better and develop better coping strategies.

While most psychotherapies incorporate both common and specific factors, Supportive Therapy (ST) is a type of psychotherapy that heavily relies on common characteristics. It focuses on building a strong therapeutic alliance, providing empathy, reassurance, and encouragement, and enhancing the client's strengths and coping mechanisms (Grover et al., 2020). Unlike more structured approaches like CBT or psychodynamic therapy, supportive therapy is less focused on specific techniques derived by specific theoretical approaches and more on providing emotional support and fostering a positive therapeutic relationship.

By choosing ST as a control group to compare its intervention with BCBT, we can also contribute to the literature that investigates the predictors of outcome in psychotherapy, specifically for suicide prevention. Despite CBT being a treatment approach with strong empirical support for various conditions, the evidence base for affirming which processes of the psychotherapy are responsible for the most relevant changes in outcome is insufficient (Wilhelm et al., 2019).

Considering the difference between BCBT and ST, this nondirective treatment that aims to help patients cope with psychological challenges, emphasizing common factors, our goal is to compare both interventions. To enhance the credibility of ST treatment, a supportive psychotherapy manual and a clinical practice guideline will be utilized (Pinsker, 2002; Grover et al., 2020).

Objectives

Primary objective: Test whether BCBT reduces time-to-first suicide attempt over 6 months relative to ST.

Secondary objectives: Compare trajectories of suicidal ideation, NSSI, depression, and anxiety; evaluate feasibility/acceptability; explore predictors and moderators of response (e.g., prior attempts, sex, age, symptom severity).

Hypotheses

1. BCBT will yield a lower hazard of suicide attempt (superiority).

2. BCBT and ST will show similar improvements in general anxiety/depression, but BCBT will outperform ST on suicide-related outcomes.
3. BCBT will demonstrate high feasibility and acceptability in this population, as reflected by satisfactory recruitment rates, session attendance, treatment adherence, and positive patient satisfaction ratings.
4. Baseline characteristics, including history of prior suicide attempts, baseline symptom severity, age, and sex, will be associated with differential clinical outcomes over follow-up.

Methods

Trial Design

Single-site, parallel-group, superiority RCT (1:1) with blinded outcome assessment and 6-month follow-up. The protocol follows the SPIRIT 2025 guidelines; reporting will follow the CONSORT 2025 guidelines and the extensions for non-pharmacological interventions and harms.

Randomization

Participants will be randomly assigned in a 1:1 ratio, stratified by sex and prior suicide attempt, using a computer-generated permuted-block randomization sequence with variable block sizes (blocks of 4 and 6) to prevent allocation prediction. The sequence will be generated by an independent researcher with no involvement in participant recruitment or outcome assessment, using validated statistical software. Participants will be enrolled by the study coordinator; treatment allocation will be released only after eligibility is formally confirmed and informed consent is obtained. Allocation concealment will be maintained through a centralized, web-based randomization module within REDCap, which withholds the assigned arm until the enrollment step is completed and locked. Neither the enrolling clinician nor the participant will have access to forthcoming allocations.

Blinding

Given the nature of psychotherapy research, blinding of participants and therapists to treatment allocation is not feasible (Cuijpers et al., 2015). However, all outcome

assessors (blinded evaluators) will be masked to treatment assignment throughout the study. Blinded evaluators are trained research assistants with no involvement in treatment delivery or session documentation. Participants will be instructed at enrollment not to disclose their treatment condition during assessment visits, and assessments will be conducted in a separate physical or virtual space from therapy rooms. Blinded evaluators will not have access to session notes, therapist logs, or any allocation-linked material. Blinding integrity will not be formally assessed; however, procedures to minimize unblinding include instructing participants not to disclose their treatment condition, conducting assessments in settings separate from therapy sessions, and restricting blinded evaluators' access to treatment-related materials.

Study setting

Institute of Psychiatry of the Hospital das Clínicas, Faculty of Medicine, University of São Paulo, is the selected study site for this randomized controlled trial.

Eligibility criteria

a. Inclusion:

1. Age 18–65 years.
2. Treatment-seeking outpatient or recent psychiatric inpatient discharge ≤ 30 days.
3. Current suicidal ideation during the past week and/or suicide attempt within the past month.
4. Ability to consent and communicate in Brazilian Portuguese.

b. Exclusion:

1. Acute psychosis or mania precluding psychotherapy participation.
2. Substance intoxication/withdrawal requiring stabilization.
3. Immediate need for inpatient admission at screening.

4. Severe cognitive impairment/neurocognitive disorder; moderate–severe intellectual disability.
5. Inability to attend visits or lack of reliable contact for safety monitoring.

Training, Supervision, and monitoring of study clinicians

Two clinicians will be assigned to provide both groups' treatments. Training will consist of sessions with didactic instruction, live supervised role plays with feedback, assigned reading materials, and supervision throughout the process. The main reference will be the BCBT manual, elaborated by Rudd & Bryan (2018), which contains clinical practice guidelines. To enhance the treatment credibility, fidelity checklists will be used and checked upon supervision by the researchers.

Concomitant Treatments

Concurrent pharmacotherapy will not be restricted during trial participation, as withholding medication in this high-risk outpatient sample would be ethically untenable. All psychotropic medications, doses, and any changes will be systematically recorded at each assessment visit. Medication use will be reported descriptively and included as a covariate in pre-specified sensitivity analyses to assess its potential confounding influence on the primary outcome. Additional individual psychotherapy outside of the study arms is not permitted during the active treatment phase (weeks 1–12); if clinically necessary, the occurrence will be documented as a protocol deviation and handled under the intention-to-treat principle. Group psychoeducation, crisis-line contacts, and emergency psychiatric interventions are permitted and will be recorded as secondary clinical outcomes and adverse events.

Outcomes

The primary outcome is suicide attempt, evaluated longitudinally to determine the efficacy of BCBT in reducing suicidal behavior. Secondary outcomes include suicidal ideation, self-directed violence, depressive symptoms, anxiety, meaning in life, subjective well-being, religiosity, quality of life, hypomanic symptoms, sleep disturbance, fatigue, and suicide-specific cognitions.

Instruments

These outcomes will be assessed using the Beck Scale for Suicide Ideation (BSI) for suicidal ideation; the Columbia–Suicide Severity Rating Scale (C-SSRS) for suicidal ideation and behavior; the SAFER and SAFER Follow-Up scales for high-risk self-harm monitoring; the Beck Depression Inventory–II (BDI-II) and Montgomery–Åsberg Depression Rating Scale (MADRS) for depressive symptoms; the Generalized Anxiety Disorder-7 (GAD-7) for anxiety; the Patient Health Questionnaire-9 (PHQ-9) for depression severity; the Deliberate Self-Harm Inventory–short form (DSHI-s) for nonsuicidal self-injury; the Duke University Religion Index (DUREL) for religiosity; the Purpose in Life Test (PIL) for perceived meaning in life; the Subjective Happiness Scale (SHS) for subjective well-being; the Short-Form Health Survey-12 (SF-12) for health-related quality of life; the Hypomania Checklist-32 (HCL-32) for hypomanic symptoms; the PROMIS Sleep Disturbance instruments for sleep-related functioning; the NIH Brief Fatigue Inventory for fatigue (NIH - BFI); Fatigue Severity Scale (FSS) and the Suicide Cognitions Scale–Revised (SCS-R) for suicide-specific maladaptive cognitions. A sociodemographic and clinical scale developed by the authors will assess participants' demographic characteristics, psychiatric history, prior suicide attempts, treatment history, and current clinical status. See Table 2 in Supplementary Material for assessment schedule.

Beck Scale for Suicide Ideation (BSI)

The Beck Scale for Suicide Ideation (BSI), developed by Beck & Steer (1991), is a self-report scale designed to identify the presence of suicidal ideation and assess associated factors, including suicide plans, behaviors, and attitudes. The scale consists of 21 items, each with three possible responses, and is used to measure the intensity of suicidal thoughts (Beck & Steer, 1991). The BSI was translated and validated for the Brazilian population by Cunha (2001), with its psychometric properties found to be satisfactory in both clinical and non-clinical samples.

Beck Depression Inventory–II (BDI-II)

The BDI-II is a 21-item self-report inventory assessing depressive symptom severity over the previous two weeks. Items cover cognitive, affective, and somatic features

of depression, scored from 0–3, with total scores reflecting severity levels. It is one of the most extensively validated measures of depression and is widely used in both research and clinical practice (Beck, Steer, & Brown, 1996). The Brazilian Portuguese version was translated and validated by Gomes-Oliveira et al. (2012), who reported strong internal consistency ($\alpha = 0.89$) and robust convergent validity, supporting its clinical and research applicability in Brazil.

Duke University Religion Index (DUREL)

The Duke University Religion Index (DUREL) is a brief 5-item instrument measuring three components of religiosity: organizational religious activity, non-organizational religious activity, and intrinsic religiosity. It was designed for epidemiological research and has demonstrated solid reliability and validity across diverse cultural contexts. (Koenig & Büssing, 2010). The Brazilian Portuguese version was translated and validated by Taunay et al. (2012).

Generalized Anxiety Disorder-7 (GAD-7)

The Generalized Anxiety Disorder-7 (GAD-7) is a widely used self-report measure designed to screen for generalized anxiety disorder and assess the severity of anxiety symptoms (Spitzer et al., 2006). Developed by Spitzer and colleagues (2006), this seven-item scale evaluates key aspects of anxiety, including feelings of nervousness, inability to control worry, and physical symptoms such as restlessness and irritability. The GAD-7 has demonstrated excellent internal consistency (Cronbach's $\alpha = 0.92$) and strong construct validity, making it a reliable tool in both clinical and non-clinical populations. In Brazil, the GAD-7 was validated by Sousa et al. (2015), who found the instrument to be effective in capturing anxiety symptoms with strong psychometric properties, thus allowing for its application in diverse settings, including primary care and specialized mental health services (Sousa et al., 2015).

Patient Health Questionnaire-9 (PHQ-9)

The Patient Health Questionnaire-9 (PHQ-9) is a brief self-administered instrument designed to assess the severity of depressive symptoms (Kroenke et al., 2001). Developed by Kroenke, Spitzer, and Williams (2001), it evaluates core symptoms of depression, such as loss of interest, fatigue, feelings of worthlessness, and

difficulties with concentration. The PHQ-9 is widely recognized for its utility in both clinical and research contexts, owing to its strong psychometric properties, including high internal consistency (Cronbach's $\alpha = 0.89$). The instrument's simplicity and reliability make it a valuable tool for screening and monitoring the severity of depression (Osório et al., 2009). In Brazil, Osório and colleagues (2009) validated the PHQ-9, confirming its effectiveness for use in primary care settings, with strong psychometric support for application across various populations.

Purpose in Life Test (PIL)

The Purpose in Life Test (PIL) is a 20-item self-report measure based on logotherapy designed to evaluate perceived meaning and purpose in life (Crumbaugh & Maholick, 1964). Brazilian Portuguese adaptations exist and have been utilized in local research; however, large-scale psychometric validation studies remain limited. The Brazilian Portuguese adaptation of the Purpose in Life Test (PIL) has been investigated in Brazilian samples, for example, by Nascimento & Dias (2019) and Câmara & Strelhow (2023).

Subjective Happiness Scale (SHS)

The Subjective Happiness Scale (SHS) is a 4-item measure that assesses global subjective well-being through self-comparisons and theoretical descriptors of happiness (Lyubomirsky & Lepper, 1999). The scale has demonstrated robust psychometric properties internationally. Brazilian adaptations have shown adequate reliability and validity in community samples.

Short-Form Health Survey-12 (SF-12)

The SF-12 is a 12-item abbreviated assessment of health-related quality of life, derived from the SF-36, which produces physical and mental component summary scores (Ware, Kosinski, & Keller, 1996). The Brazilian Portuguese version of the SF-12 was translated, adapted, and psychometrically validated by Silveira et al. (2013), demonstrating adequate reliability and validity in a population-based sample.

Hypomania Checklist-32 (HCL-32)

The HCL-32 is a 32-item self-report measure screening for hypomanic symptoms and bipolar spectrum disorders, emphasizing elevated mood, increased activity, and risk-taking behaviors (Angst et al., 2005). The Brazilian Portuguese version was translated and psychometrically validated by Vilela et al. (2011), who demonstrated adequate sensitivity and specificity for detecting bipolar spectrum disorders in clinical samples.

PROMIS Sleep Disturbance Instruments

The PROMIS Sleep Disturbance item banks evaluate subjective sleep quality, depth, restoration, and difficulties initiating or maintaining sleep (Buysse et al., 2010). Developed within the NIH PROMIS framework using item response theory, these scales offer high precision across severity levels. While Portuguese translations exist, comprehensive Brazilian validation studies remain scarce.

Montgomery–Åsberg Depression Rating Scale (MADRS)

The MADRS is widely used to assess the severity of depressive symptoms in both clinical and research settings (Montgomery & Åsberg, 1979). Composed of 10 items scored from 0 to 6, the scale evaluates symptoms such as sadness, anxiety, reduced concentration, and appetite changes. Studies have demonstrated its high sensitivity to changes in depression severity over time, and it has been validated in Brazilian samples (Fernandes, Carneiro et al., 2019). Scores will be analyzed as continuous variables and categorized according to established depression severity levels.

Columbia–Suicide Severity Rating Scale (C-SSRS)

The C-SSRS is a widely used instrument for assessing suicidal ideation and behavior (Posner, Oquendo et al., 2007). It categorizes the severity of suicidal ideation into five levels, ranging from “wish to be dead” to “active suicidal ideation with specific plan and intent.” The scale also captures the occurrence of actual, interrupted, or aborted suicide attempts, as well as preparatory behaviors. The C-SSRS identifies the highest level of ideation and suicidal behaviors since the last assessment, providing essential information for clinical decision-making. It has demonstrated strong psychometric properties (Posner, Brown et al., 2011) and, although it has not been formally validated in Brazilian Portuguese, it was previously

translated by the original authors and has been used in studies involving similar populations (Anzolin, Baldez et al., 2024).

NIH Brief Fatigue Inventory (BFI)

The NIH–Brief Fatigue Inventory (NIH-BFI) is a 7-item clinician-rated instrument designed to assess core dimensions of fatigue, including concentration difficulties, lassitude, fatigability, reduced activity, somatic symptoms, and psychomotor retardation. Items evaluate both physical and affective aspects of fatigue over the past week and are scored from 0 to 6, with higher scores indicating greater severity. Initial psychometric analyses demonstrate strong internal consistency (Cronbach's $\alpha = 0.81\text{--}0.88$) and a unidimensional structure based on principal component analysis. A formal psychometric validation in Brazilian samples has not yet been published.

Fatigue Severity Scale (FSS)

The Fatigue Severity Scale (FSS) is a 9-item self-report instrument designed to assess the impact of fatigue on daily functioning, motivation, physical activity, work, family, and social life (Krupp et al., 1989). Items are rated on a 7-point Likert scale, ranging from 1 (“strongly disagree”) to 7 (“strongly agree”), with higher scores indicating greater fatigue severity and functional impairment. The FSS has been widely used across clinical populations, including neurological, psychiatric, and chronic medical conditions, and has demonstrated good internal consistency, test–retest reliability, and convergent validity with related measures of physical and mental health. Brazilian Portuguese versions of the FSS have been used in clinical and research contexts, although large-scale psychometric validation studies in psychiatric samples remain limited. In the present study, the FSS will be used as a complementary measure to capture the functional burden of fatigue over time.

Suicide Cognitions Scale–Revised (SCS-R)

The Suicide Cognitions Scale–Revised (SCS-R) is a 16-item self-report measure assessing suicide-specific maladaptive cognitions such as perceived burdensomeness, unlovability, and hopelessness about change. Developed by Bryan and colleagues as a refinement of the original SCS, the SCS-R demonstrates strong internal consistency, a stable factor structure, and significant predictive

validity for future suicide attempts, even among individuals who deny current suicidal ideation. A formal cultural adaptation and psychometric validation of the SCS-R in Brazilian samples has not yet been published (Bryan et al., 2022).

SAFER – Self-Harm Behavior Evaluation Scale

The SAFER is a clinician-administered assessment tool designed to structure the evaluation of recent self-harm thoughts and behaviors, including urges, intent, lethality, and contextual risk factors in high-risk clinical populations. The instrument is still under development, and its psychometric properties have not yet been formally established or validated in Brazilian or international samples.

Ascertainment and Adjudication of Suicide Attempts

Suicide attempts will be ascertained at each scheduled assessment using the Columbia–Suicide Severity Rating Scale (C-SSRS), supplemented by weekly safety monitoring calls conducted by a blinded clinical assessor. For each event reported, the attempt date will be established based on participant self-report and, where available, confirmed against clinical or emergency department records. All potential suicide attempt events will be reviewed and adjudicated by a blinded independent clinician —separate from both treatment delivery and primary outcome assessment—using the standardized C-SSRS definitions of an actual suicide attempt. Only the first suicide attempt occurring after randomization will qualify as the primary outcome event for survival analysis; subsequent attempts by the same participant will be recorded as secondary outcomes but will not alter the participant’s censoring status. Participants completing the 6-month follow-up without a confirmed attempt will be censored at day 180. Those who withdraw consent or are lost to follow-up will be censored at the date of last confirmed contact. In cases of irregular follow-up intervals, the last date on which absence of an attempt was confirmed will serve as the censoring date.

Measurement Battery: Prioritization and Burden

The outcome battery was designed to be comprehensive, capturing multiple clinically relevant domains in this high-risk sample. Although several instruments overlap in content—particularly for depressive symptoms (BDI-II, PHQ-9, MADRS) and fatigue (NIH-BFI, FSS)—they serve complementary and non-redundant purposes. The BDI-II is designated the primary self-report measure of depression severity for

ranked secondary analyses; the PHQ-9 provides a brief screening complement and the MADRS a clinician-rated perspective sensitive to change. Similarly, the NIH-BFI offers a multi-dimensional clinician-rated fatigue assessment, while the FSS captures subjective functional impairment. Instruments measuring religiosity (DUREL), quality of life (SF-12), hypomanic symptoms (HCL-32), sleep (PROMIS), meaning in life (PIL), and subjective well-being (SHS) are included for descriptive and exploratory purposes and are not part of the ranked secondary outcome hierarchy. Assessment burden was considered during protocol development; instruments are administered in a fixed, piloted order, and estimated completion time per assessment visit does not exceed 60 minutes.

Sample size and power

We power the primary analysis (time-to-first attempt) using Schoenfeld's method for Cox models [32]. Assuming a hazard ratio (HR) = 0.50 (BCBT vs ST), two-sided $\alpha=0.05$, and 80% power, the number of required events is:

$$E=[\ln(HR)]^2(Z_{1-\alpha/2}+Z_{1-\beta})^2$$

If the overall 6-month event rate is ~15% in this high-risk sample (e.g., 20% ST vs 10% BCBT), then $N \approx 113$ would be required to accrue ~17 events. To accommodate 25% attrition, we plan $N=150$ (75 per group), yielding $\geq 80\%$ power under these assumptions. This sample also provides $\geq 80\%$ power to detect small-to-moderate between-group effects (e.g., standardized mean difference $d \approx 0.38$) on continuous secondary outcomes with repeated measures.

Statistical analysis plan

- Principles: Intention-to-treat primary; $\alpha=0.05$, two-sided; 95% CIs. Time zero is defined as the date of randomization. Follow-up begins at randomization and continues until first suicide attempt, death, withdrawal of consent, or administrative censoring at the 6-month assessment, whichever occurs first. Any suicide attempt occurring after eligibility screening but before

randomization will be documented as a baseline clinical event but will not count as a primary outcome event; this ensures that the risk period is aligned comparably across both arms from the moment of allocation.

- Primary analysis: Cox model estimating HR for BCBT vs ST, adjusting for stratification factors (sex, prior suicide attempt), with additional covariates (age and baseline suicidal ideation) included in sensitivity analyses. Check proportional hazards (Schoenfeld residuals); if violated, use time-varying effects or restricted mean survival time. Given approximately 17 anticipated events, including four covariates yields an events-per-variable (EPV) ratio of ~4, below the commonly recommended threshold of 10. To reduce the risk of overfitting, the pre-specified primary model will include only the two stratification factors (sex and prior suicide attempt) as covariates (EPV ~8.5). Adjustment for age and baseline suicidal ideation will be conducted as a supplementary sensitivity analysis.
- Secondary analyses: Linear mixed-effects models (random intercepts) for fixed effects: time, group, group×time; GEE/logistic models for binary outcomes (e.g., any NSSI).
- Missing data: Missing At Random (MAR) is defined as missingness that depends only on observed data; Missing Not At Random (MNAR) refers to missingness that depends on unobserved data (e.g., patients drop out because their suicidal ideation worsened). Time-to-event outcome: participants lost to follow-up will be censored at the date of last confirmed contact. Sensitivity analyses will include: (a) best-case scenario—all BCBT dropouts are assumed attempt-free (censored at day 180) while all ST dropouts are assumed to have attempted at their last contact date; (b)

worst-case scenario—the reverse; (c) tipping-point analysis—identifying the minimum assumed increase in hazard for censored BCBT participants that renders the primary result non-significant.

- Exploratory moderators (hypothesis-generating only): These analyses are explicitly exploratory. Given the projected sample size and anticipated number of primary events, treatment-by-baseline interaction tests are underpowered for definitive subgroup inference and must not be interpreted as confirmatory evidence of effect heterogeneity. Interactions of treatment with baseline factors (e.g., prior attempt, sex, age, baseline symptom severity) will be examined with marginal effects and graphical probes. Mediation (e.g., change in cognitive distortions) may be explored descriptively if data allow. All findings will be framed as generating hypotheses for future adequately powered trials.
- Multiplicity: The primary outcome (time-to-first suicide attempt) is the sole pre-specified confirmatory endpoint, tested at two-sided $\alpha=0.05$. Secondary outcomes are organized in the following interpretive hierarchy: (1) suicidal ideation (BSI, C-SSRS ideation subscale); (2) non-suicidal self-injury (DSHI-s); (3) depressive symptoms (BDI-II); (4) anxiety (GAD-7); (5) treatment feasibility and acceptability. No formal α -adjustment is planned across secondary outcomes; results should be interpreted in light of the number of comparisons made and regarded as exploratory. Exploratory moderator and mediator analyses carry no inferential weight regarding treatment efficacy and will be clearly labelled as hypothesis-generating throughout the manuscript.

Data capture and management

REDCap with role-based access, audit trails, range checks, and encrypted storage. Identifiers stored separately; audio files on secure institutional servers. Only authorized personnel access identifiable data.

Monitoring and safety

Independent Data and Safety Monitoring Board (DSMB) reviews SAEs quarterly (or ad hoc) and may recommend protocol modifications or early termination for safety. AEs/SAEs reported to CEP/CONEP per Brazilian regulation. Participants receive 24/7 emergency contacts.

Discussion

The BCBT-BR trial rigorously evaluates whether suicide-specific CBT confers advantages over common-factor ST in a Brazilian outpatient setting. Strengths include an active comparator, blinded assessment, event-focused primary outcome, therapist cross-training with fidelity checks, and cultural adaptation. Findings will guide scalable implementation of suicide-focused care in LMIC public mental health systems.

Ethics and Registration

Ethics: CONEP/Plataforma Brasil approval CAAE 88755725.9.0000.0068

Registration: ClinicalTrials.gov [registration pending; CAAE 88755725.9.0000.0068 refers to the Brazilian ethics approval (CONEP/Plataforma Brasil) and is reported separately above] 88755725.9.0000.0068

Protocol amendments: Any substantial changes will be submitted to ethics committees and updated in registries.

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- Formal analysis & Statistical plan: LB, RERF, RFD (with oversight)
- Data curation: LB, RERF
- Writing – original draft: LB, RFD
- Writing – review & editing: All authors
- Funding acquisition: None

Conflicts of Interest

The authors declare no competing interests.

Data Availability

Deidentified data, analysis code, and materials will be made available upon reasonable request following publication and in accordance with institutional and regulatory policies.

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Supplementary Material

Table 1: The structure and components of BCBT (Bryan & Rudd, 2018)

Phase	1	2	3
Sessions	1-5	6-10	11-12
Therapeutic component	Emotional Regulation and Crisis Management	Targeting Belief Systems Related to Suicide	Relapse Prevention
Techniques	Crisis Response Plan; Means restriction counseling; Sleep stimulus control; Relaxation skills training; Mindfulness skills training; Reasons for living list; Survival kitk.	ABC Worksheet ; Challenging Questions Worksheet; Problematic Patterns of Thinking Worksheet; Activity planning; Coping cards.	Relapse prevention task.

Table 2: Assessment schedule

Schedule of Assessments (CONSORT format)

Measure	T0	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12	T13	T14	T15
Sociodemographic	X															
Treatment History	X															
Weekly Follow-up		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
BSI	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
BDI-II	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
DUREL	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
GAD-7	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
PHQ-9	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
PIL	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
SHS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
SF-12	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
HCL-32	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
PROMIS Sleep	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
MADRS		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
C-SSRS		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
NIH BFI		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
FSS		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
SCS-R	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
SAFER	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
SAFER Follow-Up														X	X	X